

- a<sup>3</sup>
164. The method of claim 132 wherein delivering comprises:  
delivering the drug to myocardium.
165. The method of claim 143 wherein delivering comprises:  
delivering the drug to myocardium.
166. The method of claim 147 wherein delivering comprises:  
delivering the drug to myocardium.--

REMARKS

This is in response to the Office Action mailed on April 14, 1999. In that Office Action, claims 1-162 were pending, and all claims were rejected by the Examiner. With this Response, claims 62, 63 and 95 are cancelled, claims 57, 67, 70, 74, 75, 78, 82, 83, 86, 91, 93, 97, 103, 110, 116, 117, 120, 125, 130, 132, 133, 139, 140, 142, 143, 147, 151 and 155 are amended, claims 163-166 are added and the remaining claims are unchanged in the application.

On page two of the Office Action, the Examiner indicated that the reissue Declarations were deficient. The Examiner indicated that the Declarations did not identify the post office address of each inventor. Supplemental Declarations are provided with this response which indicate such addresses. Three of the Supplemental Declarations are executed, and applicant is currently in the process of procuring an executed Declaration from Dr. Linden. Dr. Linden's Declaration is provided in blank for the Examiner's reference. The Examiner also indicated that the Declarations did not state that the Declarants were joint inventors and identify the remaining inventors. That deficiency has also been remedied by the Supplemental Declarations. Similarly, the serial number and filing date have been added to identify the specification to which the Declarations are directed, and the city, state or foreign country of residence is also identified. Applicant has also included the language suggested by the Examiner.

Thus, Applicant submits that the Declarations are now in proper form.

Similarly, the Examiner indicated that the original patent, or an Affidavit or Declaration of Loss or Inaccessibility must be received prior to the reissue application being allowed. Applicant hereby indicates that it will provide such documents upon receiving an indication that the present claims are otherwise allowable.

At the middle of page three of the Office Action, the Examiner objected to the drawings as not showing the multiple penetrating members set forth in claims 62 and 95. With this Amendment, Applicant has cancelled claims 62, 63 and 95. Thus, Applicant submits that the drawings are now in proper form.

At the top of page four of the Office Action, the Examiner objected to claims 70, 71, 78, 79, 140, 141 and 151-154 under 35 U.S.C. § 112, first paragraph. The Examiner indicated that the specification did not provide support for "rotary motion of the penetrating member about a pivot axis, for a stylet connected to the tissue penetrating member, or for a metabolic intermediate." Applicant has amended the claims to remove the term rotary, and traverses the remainder of the Examiner's rejection.

The stylet is disclosed in FIG. 2 by the thicker tube 25, and the metabolic intermediate is disclosed at column 11, lines 11-14. Thus, Applicant submits that the specification fully supports the claims, as amended.

The Examiner then rejected claims 96-98 under 35 U.S.C. § 112, first paragraph indicating that the specification did not teach that the penetrating member could be heated, cooled, or adapted for a vibratory motion. Applicant respectfully traverses the Examiner's rejection. Heating of the penetrating member is disclosed at column 10, lines 27-31, as is cooling of the penetrating member. Similarly, column 10, lines 32-35 disclose that the penetrating member can be adapted for vibration. Thus,

Applicant submits that all of the claims are fully supported by the specification.

At the bottom of page four, and through the top portion of page five, the Examiner rejected a number of claims under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner rejected claims 57, 74, 82, 86, 91, 103, 110, 116, 120, 125, 130, 132, 140, 142, 143, 147, 151 and 155 as not including structural communication or relationships between the elongate catheter body, the tissue penetrating member and the actuator. Applicant has amended those claims to indicate that the tissue penetrating member is operably coupled to the elongate catheter body and that the actuator member is operably coupled to the tissue penetrating member. Thus, Applicant submits that the structural relationship between the elements is now fully set forth.

The Examiner then rejected claims 103, 110, 116, 120, 125, 130, 132, 140, 142, 143, 147, 151 and 155 as being indefinite because they are directed to a method for treating cardiac tissue and no steps are set forth reciting placement of the device within or at cardiac tissue. The claims have been amended to state that the catheter is navigated through vasculature to a treatment site proximate the cardiac tissue. Thus, Applicant submits that the claims are now in proper form.

The Examiner then rejected claims 67, 75, 83 and 117 as inferentially claiming certain elements. Those elements have now been positively recited in the claims. Thus, Applicant submits that the claims are in proper form.

The Examiner then rejected claim 133 stating that there was no antecedent basis for the term "the genetic material" or "the tissue". Claim 133 has been amended to depend from claim 132. Therefore, the antecedent basis for "the genetic material" is found in the final paragraph of claim 132. Similarly, claim 133 has been amended to include "the tissue penetrating member". The antecedent basis for this term is found in claim 132 as well.

The Examiner then rejected claims 134, 135, 137, 138 and 160-162 as not containing the proper antecedent basis for the term "the cardiac tissue". However, Applicant respectfully traverses the Examiner's rejection. The term "the cardiac tissue" is set forth in the preamble of each of the claims. Thus, Applicant submits that the claims are in proper form.

The Examiner then indicated that there is no antecedent basis for the term "the wall of the coronary vessel", presumably with respect to that term as found in claim 139. The claim has been amended to positively recite the coronary vessel and the wall. Thus, Applicant submits that the claim is now in proper form.

At the bottom of page five and on page six, the Examiner rejected claims 57, 59-63, 65-69, 72-74, 80-81, 86, 88-91, 93-103, 105-110, 114, 115, 120, 122-125, 128 and 129 under 35 U.S.C. § 102(b) as being anticipated by Lemelson. The Examiner also rejected claims 57, 59-61, 63, 65-69, 72-74, 80-81, 86, 88-91, 93, 94, 99-103, 105-110, 114, 115, 120, 122-125, 128 and 129 under 35 U.S.C. § 102(e) as being anticipated by Imran. On pages seven and eight of the Office Action, the Examiner rejected claims 130-159 as being obvious under 35 U.S.C. § 103(a) in view of Lemelson, and rejected claims 130-162 as being obvious under 35 U.S.C. § 103(a) in view of Imran. Of the claims rejected by the Examiner, claims 57, 74, 86, 91, 103, 110, 120, 125, 130, 132, 140, 142, 143, 147, 151 and 155 are independent claims.

Claim 57 has been amended to indicate that the tissue penetrating member is moved between the first and second positions in a direction substantially non-parallel to the catheter body. The needle in Lemelson is moved substantially parallel to the catheter body, within the lumen of the catheter. Therefore, Applicant submits that Lemelson neither teaches nor suggests the invention as set out in independent claim 57.

As with claim 57, independent claims 91, 103, 125, 130, 132, 140, 142, 143, 147, 151 and 155 all include a limitation that

the penetrating member is moved between the first and second positions in a direction substantially non-parallel to the catheter body. Thus, for the same reasons that claim 57 is allowable, Applicant submits that these claims are allowable as well.

Claim 74 states that the tissue penetrating member releases stored energy as the penetrating member moves from the first position to the second position. Applicant submits that this is neither taught nor suggested by the references cited by the Examiner. Both of the references have a slidable penetrating member which is moved under force of a plunger or similar device which has energy imparted to it. Neither of the references teach or suggest, in any manner, a penetrating member which releases stored energy in moving between the two positions. Thus, Applicant submits that neither of the references teach or suggest the invention as set out in independent claim 74. Applicant thus submits that claim 74 is allowable over the references.

Claim 110 contains a similar limitation to that found in claim 74. Therefore, Applicant submits that claim 110 is allowable for the same reasons as claim 74.

Independent claim 86 indicates that the actuator moves the penetrating member between the first and second positions in a substantially transverse path with respect to the axis of the elongate catheter body. Neither of the references cited by the Examiner teach or suggest such movement. Instead, both of the references cited by the Examiner have a plunger which moves substantially parallel to the catheter body within a lumen therein. While the needle in Lemelson does deviate slightly from an absolutely parallel path, it is not moved along a "substantially transverse path" relative to the axis of the catheter. Thus, Applicant submits that independent claim 86 is allowable over the references cited by the Examiner.

Claim 120 contains a limitation which is similar to that found in claim 86. Therefore, Applicant submits that claim 120 is allowable for the same reasons as claim 86.

Applicant also notes that claims 1-56 were only rejected based on the deficient Declarations. Therefore, Applicant submits that those claims are now in allowable form (subject to Applicant providing the original patent). In addition, Applicant notes that claims 82-85 and 116-119 were rejected based only on formal matters under 35 U.S.C. § 112. Thus, Applicant submits that those claims are allowable as well. Applicant also acknowledges that claims 58, 64, 70, 71, 75-79, 87, 92, 104, 111-113, 121, 126 and 147 were rejected based only on formal matters. Applicant submits that those claims are now in allowable form as well. Applicant again notes that upon receiving an indication that the present claims are in allowable form and are allowable over the prior art, Applicant will provide the original patent or an Affidavit of Declaration of its inaccessibility.

In conclusion, Applicant respectfully requests consideration and allowance of claims 1-61, 64-94 and 96-162.

The Commissioner is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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